IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

In Re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation
Master File No. 2:12-MD-02327
MDL No. 2327
_____/

This Document relates to:
CAROLYN LEWIS, et al.,
Plaintiffs,

-vs- Case No. 2:12-CV-04301

ETHICON, INC.,
Defendants.
_____/

DEPOSITION OF MICHAEL THOMAS MARGOLIS, M.D.

DATE: November 25, 2013
TIME: 9:20 a.m.
LOCATION: Pulone Reporting Services, Inc.
1550 The Alameda
Suite 150
San Jose, California 95126

REPORTED BY: Diane S. Martin, CSR 6464, CCRR

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Q. Prior cases you were involved in have concerned medical malpractice?
A. Correct. Individual cases.
Q. When you're paid for your work here as an expert, is that paid directly to you or some other corporation?
A. To my S Corp.
Q. What's the name of that S Corp.?
A. Michael T. Margolis, M.D., PC.
Q. Have you ever been named as a defendant in a lawsuit?
A. I have.
Q. How many?
A. I believe I've been sued five times.
Q. Can you tell me just the basics of what those cases alleged against you?
A. Sure. One was a cervical cancer. The patient expired after a hysterectomy, and you know, the allegation was that, you know, I mean, you know, she died. I mean, it was horrible.
I was dismissed, or whatever the word is.
The other was a retained sponge. I paid 20,000, I think, on that.
The other was a post-op infection that was dismissed.

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The other was a post-op subsequent prolapse in a patient who said I should have done a hysterectomy when it wasn't indicated. I got dismissed in that.
And then the other one was I was the assistant surgeon on a case in which a vascular injury occurred, and they sued everyone, and they dropped me on that one as well.
So I -- yeah, that's it. That's -- those are the ones I remember.
Q. The case where the allegation was a postoperative infection, what was the surgery at issue there?
A. It was -- I can't remember.
Q. Have you ever been involved in the drafting of a 510(k) application?
A. No, but I'm familiar with what's involved with the 510(k) application and those processes.
Q. Have you ever been involved in drafting a design history file?
A. No.
Q. You've never worked at a medical device company; correct?
A. As an employee of a medical device company?
Q. Right.
A. No, I've never been an employee of a medical

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device company. I've done consulting work, you know, again, with Cook Biomedical in Africa, but they didn't employ me.
Q. What type of consulting work did you do with Cook in Africa?
A. We worked on a fistula plug protocol.
Q. A clinical study protocol or --
A. It was a clinical study.
Q. Now, was that clinical study ultimately published?
A. Not yet. Although we -- we do have an abstract out. Boy, that just came out, too. We have an abstract out. I have to put that on my paper, on my on my CV.
Q. Where is the abstract going to be presented?
A. SUFU. The Society for Uro -- you know, Urodynamics.
Q. And that's a plug to treat fistulas?
A. Actually, the broader abstract was on our overall fistula experience, including the plugs.
Q. Are you a named author on that abstract?
A. I am.
Q. Where is SUFU going to be held?
A. You know, I'm not -- I'm not going this year. It's in -- no, it's in late February. And I can't

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remember where because I'm not going because I'm going to Uganda that week. Or right after SUFU. So I'm not going. But I know it's just before I leave.
Q. Have you ever drafted a clinical expert report?
A. Other than in a med mal?
Q. I'm sorry. When I refer to a clinical expert report, I mean a document, an expert report that's utilized in the preparation for CE marketing over in Europe.
A. Oh, no.
Q. You've never written one of those; correct?
A. No.
Q. Have you ever been involved in the drafting of a failure-modes-and-effect analysis on a device?
A. No.
Q. Have you ever been involved in drafting instructions for use in a medical device?
A. Well, depends on how you define "involved." I mean, I've lectured all over the world on complications associated with slings and things and meshes, and I've lectured to the FDA on it. So I -- I think I am uniquely involved in the process.
Q. I guess my question was though, have you ever been involved in the drafting of an instructions for

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use for a medical device?
A. Well, again, other than lecturing to the FDA and lecturing all over the country on the risks associated with slings in particular and meshes, I haven't written it down, but I have lectured all over on it.
And, of course, I'm familiar with the IFUs as I use them every day in my practice as well as in my teaching, including teaching to residents and fellows and attendings physicians all over the country. So I use them. And I lecture on them regularly.
Q. I'm sorry, objection. Move to strike. That wasn't my question.
My question was, have you ever been involved in drafting an IFU?
A. Well, I'm going to hold to my answer, because that's -- that's the answer.
Q. I'm not asking -- I know you were involved with the FDA. You were there. You talked to the ag com. I'm familiar with all of that. My question is very straightforward and simple.
Have you ever been involved in drafting an IFU?
A. The answer is other than lecturing on it and using it and using it as part of my teaching, no.

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Q. Move to strike everything before "no."
When is the last time you looked at a Gortex IFU?
A. I haven't used -- haven't looked at a Gortex IFU recently. I've been using it for long enough and it hasn't changed.
Q. When is the last time you looked at an IFU for the Boston Scientific Xenform sling?
A. Within the last year.
Q. When is the last time you looked at the Coloplast human cadaveric fascia IFU?
A. Probably within the last two years.
Q. When is the last time you looked at the Boston Scientific Repliform IFU?
A. Last time I used it. Several years ago.
Q. Would you typically look at an IFU every time you do a procedure?
A. Any new instrument or material that I use that's new to me or that I'm teaching about, I will utilize the IFU in my analysis and my expertise or my usage of it until, of course, I get to the point like with Gortex where nothing has changed with Gortex for a long time. So I don't use that. IFU since nothing has changed. But with newer devices and newer products that I start using and when I teach, I utilize the IFU.

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Q. What about the SIS product for Cook that you used, the porcine pig small bowel, when is the last time you looked at the IFU for that?
A. Back recently. I mean, that's -- that's a recent study that we were working on. In fact, I was -- I mean I was, you know, intimately involved in the -- in working with the engineers on that product because I was the technical surgeon who was helping them work out their operative protocols on that device that we were trying to develop. We were building a new fistula plug.
Q. That's not the SIS product for Cook; is it?
A. Cook has an SIS product for rectovaginal fistulas. We were working on a novel fistula plug for vesicovaginal fistulas. We were working to transpose their RVF plug to a VVF plug.
Q. The SIS product by Cook, which was the porcine pig small bowel, I thought that was a sling-type material you had used a few times?
A. Okay. So good question. It's the same material. The sling -- the SIS material, the porcine bowel submucosa can be used in the form of a sheet for hernia and prolapse. It can also be made into a plug, which is used for fistulas. So they use the same material, but in different applications.

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Q. What Ethicon products besides Prolene have you used in your career?
A. Ethicon? I used their trocars. I love their trocars. Some of their instruments are good instruments. Needle drivers and the like. But most of what I use from Ethicon is the trocars or the preferred trocars. I argue with the hospitals to use them.
Q. Is that the laparoscopic trocars?
A. The laparoscopic trocars, yeah. I argue. I try to get the hospitals to use them. They like to get the cheaper ones, but the Ethicon are better.
Q. Besides the TVT and TVT-O IFUs, have you reviewed other manufacturers' IFUs --
A. I have.
Q. -- for polypropylene slings?
A. I'm sorry. I shouldn't have interrupted you. Yes, I have.
Q. Which ones?
A. Every single one of the synthetic slings out there.
Q. Have you ever been involved -- strike that.
Have you ever participated in the drafting of a patient brochure?
A. A patient brochure?
Q. And I'm going to cast a broad net. I mean for

anyone. Such as AUGS, AUA, SGS, the hospital systems or industry.
A. Well, I mean, I've used them -- I've drafted them at Stanford when I was chief of the division. Patient brochures. Yeah, sure, as a matter of fact, I did back at Stanford.
Q. That was when you were the chief between 1996 and '97?
A. Correct. I draft patient brochures for my office as well.
Q. Is that a patient brochure you draft for your patients?
A. Yes.
Q. The patient brochures you draft for your office, what procedures do they cover?
A. They cover the operative procedures that I do in general.
Q. Do you have a specific one for stress urinary incontinence surgeries, or is it even to the level of, you know, pubovaginal sling with a cadaveric material?
A. No.
Q. Versus a Burch?
A. Right. Thank you.
No.
It's for my surgeries in general.

Q. For how long have you drafted your own patient brochures for your patients?
A. Since 2007.
Q. Do you keep copies of them?
A. I do.
Q. I'd like to make a request for those.
A. Please. If you would, if somebody could just remind me.
Q. Okay. Do the patient brochures that you have currently identify all the risks with the surgeries?
A. The -- my consent form does, but the brochure that I have is for postoperative management. So the -- I guess the answer is, I have a consent form that goes over all the risks that I previously described. It's a separate document, but I can get that to you as well if you'd like.
Q. The patient brochure, is that something separate than the consent form, it sounds like?
A. It is.
Q. And is that patient brochure specific to only the post-op management of -- strike that.
Is that patient brochure specific to the post-op period of a surgery?
A. Generally speaking, yes.
Q. When you were at Stanford, did you draft any

patient brochures during that 1996 to '97 time period concerning stress urinary incontinence surgeries?
A. Yes, I did. It was regarding prolapse and incontinence.
Q. Do you happen to still have a copy of that?
A. No, I don't. I think it was all lost in a fire somewhere.
Q. You've never been an employee of the FDA; correct?
A. No.
Q. Have you ever been a consultant to the FDA?
A. No.
Q. Have you ever submitted adverse event reports to the FDA?
A. Other than my meeting in Gaithersburg, Maryland, no.
Q. I'm sorry?
A. Other than my meeting, you know, the FDA hearing. That's the only involvement I've had with the FDA.
Q. You know there's specific forms where a surgeon or a doctor can fill out an adverse event report and submit it to the FDA; correct?
A. Correct.
Q. You haven't submitted any of those; correct?

A. That's correct.
Q. What was your undergrad in?
A. My undergraduate degree or where I went to school?
Q. Yes, your grad.
A. Degree was psychology, believe it or not.
Q. Have you ever done any bench research on polypropylene?
A. I have not.
Q. Have you ever done any laboratory research on polypropylene?
A. Not on polypropylene.
Q. What have you done laboratory research on?
A. I did some chemical laboratory research back in undergrad on substituted alpha pyrones. That was my first publication.
Q. What is that?
A. Beta lactams. It's a chemical. It's a relative of the cephalosporin class of antibiotics.
Q. Do you have a background in the study of polypropylene chemistry?
A. Other than the training I got in premed and my study of organic chemistry and industrial chemistry which I took courses in, no.
Q. You don't consider yourself to be a

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doctors across the United States?
MR. CARTMELL: Object to the form.
THE WITNESS: It has -- it was a surgical option amongst a variety of surgical procedures that were and still are available.
BY MR. SNELL:
Q. The plan to offer and to ultimately use the TVT retropubic sling in Mrs. Lewis' case was not against the standard of care; correct?
A. As of that time, no.
Q. No, it was not against the standard of care?
A. No. Correct. I was agreeing with you.
Q. And as we sit here today currently, the use of TVT slings to treat stress urinary incontinence surgically, that's not against the standard of care; correct?
A. It is used by some physicians and fewer and fewer all the time, but it is still an accepted modality in the repertoire.
Q. You're aware that the American Urologic Association has stated that midurethral slings are a suitable surgical option to treat stress urinary incontinence?
MR. CARTMELL: Object to the form.
THE WITNESS: Well, as a member of the

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American Urologic -- I'm sorry, AUA?
BY MR. SNELL:
Q. Yes, the American Urology Association.
A. The American Urologic Association? Well, since I'm a gynecologist, I don't really pay a lot of attention to what the AUA says. So I don't really --
Q. You don't?
A. The AUA is the AUA. They're not -- they're not joining us.
Q. You're aware that the AUGS, American Urogynecologic Society, has stated that synthetic midurethral slings are the current gold standard?
MR. CARTMELL: You do not object to the form?
THE WITNESS: As a member of AUGS, I don't agree with that.
BY MR. SNELL:
Q. But you're aware that AUGS has stated that in a position statement?
A. I'm aware that AUGS members do slings, Burches, collagen injections, robotic Burches, and organic slings as well as synthetic slings, and that the TVT sling in particular is losing favor because of its high complication rate, but it is still an accepted option.
But as a member of AUGS, I do not agree that

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it is considered the gold standard. And if some people say it, they don't speak for everyone in AUGS because I am an AUGS member and have been since 1994.
Q. I believe you testified that the TVT is being used less often because of complication rates.
Can you point to any data, studies, any surveys by any professional body which supports that statement?
A. I lecture all over the country. I'm all over the world, and I see people running away from it in droves. Data, published data, not yet. It will be there soon enough.
Q. Are you aware of literature showing actually that between 2000 and the present, surgeons have stopped doing more and more colposuspensions and have started doing more sling procedures with synthetic slings?
MR. CARTMELL: Object to the form.
THE WITNESS: There are some that argue that. Those are biased studies that are not accurate. I don't believe that's true. I don't believe that's true at all.
BY MR. SNELL:
Q. Why do you say they're biased studies?
A. Well, I mean, come on. The study you showed

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me earlier was flawed, according to Dr. Karram. I mean it was the methodology himself. He admitted the methodology on the study that looked at the pubovaginal sling versus TVT, the methodology was flawed. There's a lot of flaws in the studies that are being published right now on TVTs. A lot of industry bias.
I mean, let's face it. The industry bias is there. A lot of these authors are paid consultants, and you know, are publishing data that is not accurate. So I disagree with what you said, and I'm going to hold to my answer.
Q. So you think any author who's been paid anything by industry is biased?
A. I did not say that. And I do not think that.
Q. You've been paid; correct?
A. I have been.
Q. And are you biased towards Boston Scientific?
A. No, I'm not. I use the Boston Scientific instruments, the Capio devices and the Xenform a lot, but I am not bought or sold by those people. I use what I use because I find they work.
Q. Is it your testimony that other than you, any other doctor out there who gets money from companies and writes about their product is biased?
MR. CARTMELL: Object to the form.

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MR. CARTMELL: Objection. Asked and answered.
BY MR. SNELL:
Q. -- for --
MR. CARTMELL: Oh, sorry.
BY MR. SNELL:
Q. -- postoperative pain.
A. The same answer. I mean, all of my answers are postoperative pain. I mean, you can't have pain if you're asleep, right?
Q. I mean in the postoperative period. That's what I'm talking about. We first talked about chronic, permanent pain, okay? And you weren't able to identify a study; correct?
MR. CARTMELL: Well, hold on. He said he didn't think studies had been done.
MR. SNELL: That's fine.
BY MR. SNELL:
Q. Your answer is your answer.
But now I'm moving on to we're not talking chronic pain. But we're talking about pain in the postoperative period.
A. So your question is?
Q. So my question, let me repeat it.
Are you aware of any studies, or can you point to any studies that support your opinion that show a

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statistically significant increased risk of postoperative pain for the TVT compared to Burch or the fascial slings?
A. Immediate postoperative pain; not chronic?
Q. Correct.
A. Not that I know of. I mean, everyone has pain after surgery for a couple of -- for four to six weeks.
Q. You say the TVT could cause life-long risk of erosions; correct?
A. Absolutely.
Q. There can be erosions with biologic materials; correct?
A. Erosions with biologics are short lived and self limiting. They resolve on their own. When in the rare event that they do occur.
Q. There can be a life-long risk of suture erosion if one uses a permanent suture in suspension procedures; correct?
A. You mean like a Burch?
Q. Sure. You're using permanent sutures in a Burch. There can be erosions that occur years and years later; correct?
A. Have I seen that? Once. It's virtually a reportable event.
Q. You know the Urinary Incontinence Treatment

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Network received funding for this study from the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Child Health and Human Development? Do you see that?
MR. CARTMELL: What page are you on?
MR. SNELL: 2153.
MR. CARTMELL: 2153.
THE WITNESS: Yeah, but if you go further, then Dr. Zyczynski receives funding from Ethicon, J&J. You know, we can go down the list. Others received funding from AMS.
BY MR. SNELL:
Q. Are you saying the publications by the Urinary Incontinence Treatment Network shouldn't be trusted because of disclosures that they identified?
MR. CARTMELL: Object to the form.
THE WITNESS: No. I mean, if you're talking about potential bias, I mean, this study lists potential bias, right. There are numerous individuals here who received money from J&J.
Now, that's the purpose of disclosure is to report to potential bias. And there are numerous authors here who have received funding from J&J and Ethicon. So I mean, it is written.
Q. But this study was supported not by Ethicon,

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but by the government; correct?
A. It was supported by, as you stated, and written by people who received funding from industry.
Q. And Dr. Zimmern was one of the people who was an author on this paper; correct?
A. Correct. I'm sorry. Yes.
Q. Same Dr. Zimmern who treated Mrs. Lewis; correct?
A. Correct. Philippe Zimmern.
Q. And that study shows continence rates with the Burch which are much lower than the success rates you quote in your report; correct?
A. And reported all through the literature over the last 60 years, correct.
Q. I don't see that you cited to any reference or references when you identified the success of the Burch. Can you tell me what study or studies you were citing to?
A. Oh, sure. Let's see. I'm just going to give you the numbers in my reference list, rather than read the entire quote.
33.
Q. Let me just get to it.
A. Sorry, page -- well, it's in the 30s.
Q. Okay.

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A. Well, that's five-year followup. I have to -- you know what? I don't want to quote from this article from C.S. Liu, but that was a five-year study, and the rates were good. The 80 to 90 percent. So Linda's study there just doesn't fit.

And I think they were using other definitions in that study. They kind of acknowledged in the predicate study that there were -- there were -- there were problems with their study, and we can get into that if you want me to go off that original study.

Q. The Liu study you talked about, it didn't have over 500 patients; correct?

A. I don't think so.

Q. And it wasn't an RCT; correct?

A. It was not.

Q. And it wasn't a multicenter randomized control trial; correct?

A. I don't think so.

Q. I didn't see in your report anywhere that you indicated what the two-year, five-year, ten-year continence rates were with the pubovaginal sling.

A. I did not put that in there.

Q. Have you ever -- have you surmised or come up with the continence rate at those different periods of time for the pubovaginal sling, or is that not

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something you're going to come and testify about at trial?

A. No. I mean, the generally-accepted success rate for a Goebell-Stoeckel sling at ten years is around 88 percent. Burch is about 90 percent.

Q. When you say "generally accepted," you mean generally accepted by who?

A. That's reported in the literature. The body of work over the last 60 to 90 years. 90 if you include the sling. Because the sling first came out in 1907.

Q. So you think that overall at ten years the pubovaginal Goebell-Stoeckel sling efficacy rate is 88 percent?

A. I don't think. That's what's reported in the literature.

Q. In one study; correct?

A. No. No, more than that.

Q. So the 88 percent is your analysis of the literature?

A. No. It's reported in the literature. The procedure has been around for 90 years; right? 1907. We have a lot of data on that.

Q. What are you referencing as this 88 percent for the sling?

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A. What's reported in the literature.

Q. At ten years?

A. At ten years.

Q. Is there a study or a book or something that you're referring to? I'm just asking because I've never seen this 88 percent.

A. Those are all references. Well, they're all referenced from the peer-reviewed journals.

Q. Who concluded it was 88 percent at ten years?

A. I'd have to go back and get the quote, but it's in there. It's in the peer-reviewed journals. It's in the textbooks.

Q. And the Burch, 90 percent success at ten years, is that your opinion, or is that something you've read?

A. I think I've already answered this question several times. And I'll say it again. It is reported in the literature numerous times. The procedure has been around for over 60 years. We have more than 60 years of data on the Burch and its predicate procedure, the MMK. We have 90 years of data on the traditional sling.

These procedures have been around. There have been numerous, countless reports in the peer-reviewed journals on their excellent success rates.

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The Albo study and the Brubaker studies are completely inconsistent with the giant volume of studies in the repertoire that say otherwise, and the authors of the Albo study even acknowledge that they have numerous -- that there are problems with their study.

Q. As you sit here today you're unable to point to any studies, any specific studies that show an 88 percent success rate with the pubovaginal sling at ten years; correct?

A. Goebell-Stoeckel sling, I don't have any studies right now in front of you.

Q. That's fine.

A. Or --

Q. Or on your exhibit list or anywhere else?

A. No, I do not include those references.

Q. And as you sit here today you can't point to any studies on the Burch where ten-year continence rates were 90 percent?

A. This is what I've been lecturing on since 1992. All of my lectures are based on studies that I pulled out of the peer-reviewed journals. They're there. The data is there.

Q. So if I go to the peer-review literature and I find one study with an 88 percent success rate with the

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short term.
Q. Now, this is an actual Cochrane review from 2011; right?
A. That is correct. Cochrane review.
Q. So by 2011, these authors in the Cochrane review are saying that the trials are short term. They're moderate to moderate-to-low quality. And they're not able to necessarily make conclusions related to long-term complications with the mesh slings; correct?
A. Correct.
Q. It then states, if you go under the ÿConclusions" section, it specifically states that "randomized control trials have limitations in identifying true complication rates."
Do you see that?
A. I do.
Q. Now, these studies that they're looking at, their primary end point was to look at whether or not they were effective; right?
A. Effectiveness. But they didn't look at complications and problems. They didn't look at complications. Long-term complications.
Q. Right. They would report on complications, but the authors are stating here that randomized

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control trials have limitations in identifying those; correct?
A. Yes.
Q. And it states, "However, there is little evidence about the long-term effectiveness or the chance of adverse effects such as tape erosions."
Do you see that?
A. Yes.
Q. And then it states, "Nor is it clear how to treat women after a tape procedure fails"?
A. That is stated.
Q. What does that mean to you?
A. Well, there is no well-established standard on how to deal with tape complications. That's an area of medicine that really hasn't evolved yet. It's only starting to. It's only starting to develop as we learn how to take out these slings. That's a whole new frontier that's about ready -- that we're on the edge of.
Q. Do you have an opinion regarding whether or not Ethicon adequately warned physicians and/or patients about the risk of needing the mesh tape to be removed and how to treat that when it occurred?
A. I do.
Q. And what is that?

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A. Ethicon failed to warn physicians and patients of the risks and complications inherent in the TVT device, and that failure has led to a plethora of complications and problems. They have failed to do their due diligence and warn of the pros and cons, the pros and cons of their procedure.
Q. And those opinions and others are further set out in your report; is that correct?
A. They are. And they are based upon my review of all of the documents that are described in my report.
MR. CARTMELL: Okay. I don't have anything else. Thanks.
MR. SNELL: A couple back.
MR. CARTMELL: I don't know, you didn't save much of the seven hours for your recross.
MR. SNELL: You've gone into stuff so I'm going to go ahead and go into it.
FURTHER EXAMINATION
BY MR. SNELL:
Q. Go back to Exhibit 8, the Albo study.
A. Okay.
Q. You were asked some questions about the bias of the authors in this study; correct?
A. I was.

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Q. Do you know any of these authors?
A. I met Linda Brubaker many moons ago. I've met Peggy Norton many moons ago at professional meetings. I don't know them beyond just meeting at professional meetings.
Q. Is it your testimony that Linda Brubaker is pro mesh?
MR. FREESE: Object to the form of the question.
THE WITNESS: I haven't said whether she's pro or con.
BY MR. SNELL:
Q. Is it your testimony that Linda Brubaker has a bias towards making the Burch procedure and the fascial sling look bad to benefit industry?
MR. CARTMELL: Object to form.
THE WITNESS: I haven't -- I'm not identifying her as good or bad in any sense of the form. I'm just acknowledging that there are biases that are identified in this document that the authors themselves acknowledge, okay. It's what they wrote down on page 2153. They acknowledge their support, and that's potential bias. That's all.
BY MR. SNELL:
Q. And is it your opinion or belief that these

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authors have changed or altered the data in any way in this study to make the Burch or the fascial sling look bad?
A. The FDA mandated that people put their potential biases in because they were concerned that there might be such a thing. These authors acknowledged their potential biases. I commend them for doing that. They're out there. They're in black and white. There's a potential bias.
I'm not pointing a finger at Linda or Peggy, but they do acknowledge that they have potential biases. These authors admit. And not just Linda or Peggy. All of these authors have put in their potential conflicts of interest. I acknowledge them. It's there for everyone to see. You'll have to judge on your own.
Q. I understand. But I'm just asking you, is it your opinion that these authors, because of the bias or potential bias they've written and disclosed in the New England Journal, that they have changed the data some way such to make the Burch and the fascial sling procedures look bad?
MR. CARTMELL: Object to the form.
THE WITNESS: Well, those are your words. I'm not going to in any way, shape or form associate myself

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with those words. Okay.
BY MR. SNELL:
Q. So you don't hold that opinion?
A. I don't agree with what you said.
Q. It's a question. It's not -- I didn't say it.
A. You're trying to put -- you're asking --
Q. It's a question. He asked you about bias. You went on and on about how all these folks have relationships with industry. My question is --
A. They do.
Q. Do you have an opinion that that relationship with industry and the potential biases they've written down here had an effect on this study?
MR. CARTMELL: Object to the form. I will tell you we're not going to have him offer that opinion.
MR. SNELL: Well, you've already opened that door.
MR. CARTMELL: No, I haven't. He has testified that there are biases that are listed, potential biases listed. Potential biases is what he has said. You obviously know he hasn't reviewed any of the data. He's not going to come in and say that they manipulated the data. The authors have said they have

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potential biases and, in fact, we looked in the substance of the report and they identified a potential bias there as well. That's all he said. He's not coming in and saying they manipulated.
MR. SNELL: He said more than that. He said that data can't be trusted.
MR. CARTMELL: I don't think he said it.
MR. SNELL: The record will speak for itself.
MR. FREESE: Then why are you guys arguing about it? All he acknowledged was the authors acknowledged their bias.
THE WITNESS: All I can say is that their data --
MR. CARTMELL: Hold on.
He's told you several times throughout this that one of the things he looks at when he's looking at literature is bias or potential bias, and that's all he's testifying to. He's looked at it here.
BY MR. SNELL:
Q. Are you going to come into trial and testify that one cannot rely on these results in this study by the Urinary Incontinence Treatment Network because of their potential disclosed bias?
MR. CARTMELL: Object to the form.
THE WITNESS: I'm going to say what I've

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already said.
BY MR. SNELL:
Q. Okay. One of the things plaintiff's counsel pointed you to in the Albo study is at page 2152. They talked about all the patients in the study received care at tertiary care centers. Do you recall that?
A. I see it right here.
Q. One of the things he read to you was in women with stress-predominant incontinence; correct?
A. In women with pure or stress-predominant incontinence.
Q. Right. And Mrs. Lewis has stress-predominant incontinence; right?
A. That is correct.
Q. Next page, plaintiff's counsel pointed you to the statement about rigorous comparative trials being needed; correct?
A. Could you direct me to the --
Q. Page 2153.
A. Whereabouts?
Q. The left column, pretty much dead center.
A. Oh, here we go. Gotcha.
Q. And can you identify rigorous comparative trials that you believe were done on the Burch and the pubovaginal sling --

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MR. CARTMELL: Objection. Asked and answered.
BY MR. SNELL:
Q. -- that you relied on?
MR. CARTMELL: Objection. Asked and answered.
THE WITNESS: The whole body of work that's been in publication for decades.
BY MR. SNELL:
Q. Page 2151 plaintiff's counsel pointed you to.
A. -- 2151.
Q. Yes. The statements "Success rates in our trial were low as compared to those in previous studies"?
A. I see that.
Q. Plaintiff's counsel read that to you; correct?
A. I see it, of course.
Q. And numbers 9 and 10, footnotes references 9 and 10; correct?
A. Correct.
Q. Turn back to footnotes 9 and 10. You see those are two Cochrane reviews, the first by Bezerra, the second by Lapitan?
A. Correct.
Q. Bezerra was a Cochrane review on the traditional suburethral sling; correct?
A. Correct.

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Q. You read that?
A. I've read it in the past. I can't quote it word for word.
Q. Lapitan was a Cochrane review on the open retropubic colposuspension; correct?
A. Correct.
Q. That's the Burch; correct?
A. Correct.
Q. And in those Cochrane reviews that plaintiff's counsel pointed you to, do you recall how they characterized the quality of the data?
A. Oh, if you have those articles in front of you and would like to share them with me, I would love to see them.
Q. Well, you mentioned that in the Ogah Cochrane review they talked about the quality of the data being variable. Do you remember if similar statements were made in the other Cochrane reviews?
A. I mean, again, if you have those, I'll be happy to opine on them right here, but I'd like to see those articles before I make any comment.
Q. You don't recall that?
A. I've already answered your question twice now. I'll say it again. If you have those articles, I'd be happy to opine on them. I'm not going to speculate.
Q. My question is, do you recall if they said anything about the quality of the data in those Cochrane reviews?
A. Okay. For the fourth time, I can't opine on those articles without having them in front of me.
Q. I'm not asking you to opine.
MR. CARTMELL: He's just asking you if you recall what they say.
THE WITNESS: No. I don't recall. That's obviously why I'm saying I don't want to opine.
BY MR. SNELL:
Q. Okay. Plaintiff's counsel pointed out the statement about that in the Ogah Cochrane review that many of the studies were one-year RCTs?
A. Are we going to another exhibit now?
Q. I think it's the one you have in front of you. The Ogah Cochrane review.
MR. CARTMELL: No, that's different.
THE WITNESS: I have Albo.
BY MR. SNELL:
Q. You know, we can stick with Albo. So for the Bezerra and the Lapitan.
A. The reference is 9 and 10.
Q. Yes, for the Cochrane reviews that plaintiff's

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counsel pointed you to, do you know whether the majority of the studies looked at in those Cochrane reviews were one-year RCTs?
A. Again, I don't have that information in front of me so I'd be happy to answer that if I have them in front of me. I don't know. I don't know as I sit here right now.
Q. If the same type language was in those Cochrane reviews, you would give the same criticism that you gave with regard to the midurethral sling; correct, with regard to the majority being 12-month RCTs?
A. I would read the entire article and opine on the entire article as a generalized entity. I would not go and look at one specific thing in the article. I'd look at the entire article and opine upon it.
Q. You told plaintiff's counsel that regardless of what you saw in the materials I presented to you, that it's your belief that traditional slings are more effective than the TVT; correct?
A. I said traditional slings have the success rate of roughly 88 percent.
Q. I thought you testified to plaintiff's counsel that in your opinion traditional slings are more efficacious than TVT.

A. Well, it depends on which -- whose data you want to reference on the TVT. I think that they were better. I think they work better, and I think that they have a lower complication rate. I know they do.
Q. And as we sit here though, you can't point to any comparative studies that support that opinion?
A. Other than all the studies I referred to throughout today's deposition.
Q. As we sit here today, there have been no comparative studies that we pointed to or referred to or that are identified in your expert report or reliance list that state the traditional sling is more effective than TVT; correct?
A. Not that I have referenced.
Q. And you have not referenced, nor can you identify any comparative studies that show that the Burch is more effective than the TVT; correct?
A. I have not referenced that at this -- I don't have anything standing in front of me that I can -- that I will use as a reference.
Q. Did you review any of the professional education slide decks for the TVT product?
A. The professional education?
Q. Slides.
A. Slides?

Q. For TVT retropubic.
A. That were given out to a lot of physicians during the -- during its early years?
Q. Going back to, yes, going back to late 1990s, even to the present.
A. Yes, I have. I have looked at those.
MR. SNELL: Okay, that's good. Thank you.
THE WITNESS: Thanks.
MR. FREESE: Can we just -- I think I'm making sure to put this on the record.
Anything that Dr. Margolis has testified about today that is general as opposed to being specific to Ms. Lewis, we're going to agree that that -- those opinions and testimony are as if they were given in the Batiste case.
And also like we did before, Burt, any questions that Michael has tomorrow that are general versus Batiste specific, we're going to agree that they are able to be used in the Lewis matter as though they were given in the Lewis deposition.
Are we all good on that?
MR. BROWN: Agreed.
MR. SNELL: I'm fine with that.
MR. FREESE: Thanks.
(The deposition of MICHAEL THOMAS MARGOLIS, M.D.

was adjourned at 6:45 p.m. this date.)
--- oOo ---

REPORTER'S CERTIFICATE

The undersigned Certified Shorthand Reporter licensed in the State of California does hereby certify:

I am authorized to administer oaths or affirmations pursuant to Code of Civil Procedure, Section 2093(b), and prior to being examined, the witness was duly administered an oath by me.

I am not a relative or employee or attorney or counsel of any of the parties, nor am I a relative or employee of such attorney or counsel, nor am I financially interested in the outcome of this action.

I am the deposition officer who stenographically recorded the testimony in the foregoing deposition, and the foregoing transcript is a true record of the testimony given by the witness.

Before completion of the deposition, review of the transcript [X] was [ ] was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

In witness whereof, I have subscribed my name this ____ day of _____, 2013.

_____

DIANE S. MARTIN, CSR No. 6464

REPORTER'S CERTIFICATE

The undersigned Certified Shorthand Reporter licensed in the State of California does hereby certify:

I am authorized to administer oaths or affirmations pursuant to Code of Civil Procedure, Section 2093(b), and prior to being examined, the witness was duly administered an oath by me.

I am not a relative or employee or attorney or counsel of any of the parties, nor am I a relative or employee of such attorney or counsel, nor am I financially interested in the outcome of this action.

I am the deposition officer who stenographically recorded the testimony in the foregoing deposition, and the foregoing transcript is a true record of the testimony given by the witness.

Before completion of the deposition, review of the transcript [X] was [ ] was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

In witness whereof, I have subscribed my name this ____ day of _____, 2013.

_____

DIANE S. MARTIN, CSR No. 6464

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

MICHAEL THOMAS MARGOLIS, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public